4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0056]

Biofilms, Medical Devices, and Anti-Biofilm Technology--Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Biofilms, Medical Devices, and Anti-Biofilm Technology--Challenges and Opportunities." FDA is cosponsoring this workshop with the Center for Biofilm Engineering of Montana State University. The purpose of the public workshop is to initiate dialogue between academia, industry, and U.S. Government scientists on the science of developing products to address biofilm formation. Topics of discussion include current scientific and medical research on biofilms, their impact on medical devices, and biofilm prevention strategies and their public health impact.

DATE: The public workshop will be held on February 20, 2014, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Geetha Jayan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3622, Silver Spring, MD 20903-0002, 301-796-6300, email: geetha.jayan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. February 7, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, (email: susan.monahan@fda.hhs.gov or phone: 301-796-5661) no later than February 7, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. (EST) on February 6, 2014. Early registration is recommended because Webcast connections are limited.

Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after February 14, 2014. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to obtain information on biofilms and anti-biofilm technology on medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is March 20, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

I. Background

Biofilms play a key role in the development of device-related and other healthcare associated infections. Published literature indicates that biofilms are a major culprit in the development of resistant infections. However, the biochemical and physiochemical characteristics of biofilms are not widely understood.

With the increasing use of implanted and indwelling devices, understanding biofilm development on these devices and factors that impact biofilm formation is critical. Research on the basic science of biofilms may provide insight on device-associated biofilms, ultimately advancing research on technologies that are intended to prevent biofilm formation.

This public workshop seeks to share scientific information between academia, industries interested in developing products to address biofilm contamination, and U.S. Government scientists.

II. Topics for Discussion at the Public Workshop

FDA seeks to address and receive comments on the following topics:

1. Research on biofilms and their public health impact.

2. Challenges faced by the scientific community, government, and industry on addressing biofilm contamination of medical devices.

3. Critical areas of research that will address the scientific and clinical challenges faced by the stakeholders when developing technologies that are intended to prevent biofilm formation.

This public workshop may also form the basis for future discussions related to novel biofilm prevention technologies that could benefit U.S. public health.

Dated: January 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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